

- 473 • A patient Medication Guide is available for METOZOLV ODT and printed at the end of the prescribing  
474 information. Instruct patients, families, and caregivers to read the Medication Guide and assist them in  
475 understanding its contents.
- 476 • Inform patients or their caregivers of serious potential issues associated with metoclopramide use such as  
477 tardive dyskinesia, extrapyramidal symptoms, and neuroleptic malignant syndrome. Advise patients to inform  
478 their physician if symptoms associated with these disorders occur during or after treatment with METOZOLV  
479 ODT.
- 480 • Inform patients that METOZOLV ODT may cause drowsiness, dizziness, or otherwise impair mental alertness  
481 or physical abilities required for the performance of hazardous tasks such as operating machinery or driving a  
482 motor vehicle. Sedation may be more pronounced in the elderly.
- 483 • Inform patients that the most common adverse reactions in patients treated with METOZOLV ODT or other  
484 metoclopramide-containing products are headache, nausea, vomiting, tiredness, sleepiness, dizziness, and  
485 restlessness.
- 486

Manufactured by:  
Catalent UK Swindon Zydis Limited  
Swindon, UK

Manufactured for:  
Salix Pharmaceuticals, Inc.  
Morrisville, North Carolina

487  
488 VENART-xxx-x/ Sep 2009

490  
491 MEDICATION GUIDE

492  
493 **METOZOLV™ (MĔ-tō-zolv) ODT**  
494 (metoclopramide hydrochloride)  
495 **Orally Disintegrating Tablets**

496  
497  
498 Read the Medication Guide that comes with METOZOLV ODT before you take it and each time you get  
499 a refill. There may be new information. If you take another product that contains metoclopramide (such as  
500 REGLAN tablets, REGLAN ODT, REGLAN injection or metoclopramide oral solution), you should read  
501 the Medication Guide that comes with that product. Some of the information may be different. This  
502 Medication Guide does not take the place of talking with your doctor about your medical condition or  
503 your treatment.

504  
505 **What is the most important information I should know about METOZOLV ODT?**

506 METOZOLV ODT can cause serious side effects, including:

507 **Abnormal muscle movements** called tardive dyskinesia (TD). These movements happen mostly in  
508 the face muscles. You cannot control these movements. They may not go away even after stopping  
509 METOZOLV ODT. There is no treatment for TD, but symptoms may lessen or go away over time after  
510 you stop taking METOZOLV ODT.

511 Your chances for getting TD go up:

- 512 • the longer you take METOZOLV ODT and the more METOZOLV ODT you take. You should not  
513 take METOZOLV ODT for more than 12 weeks.
- 514 • if you are older, especially if you are an older woman
- 515 • if you have diabetes

516 It is not possible for your doctor to know if **you** will get TD if you take Metozolv ODT.

517 Call your doctor right away if you have movements you can not stop or control, such as:

- 518 • lip smacking, chewing, or puckering of your lips
- 519 • frowning or scowling
- 520 • sticking out your tongue
- 521 • blinking and moving your eyes
- 522 • shaking of your arms and legs

523

524 See the section “What are the possible side effects of METOZOLV ODT?” for more information about  
525 side effects.

526

### 527 **What is METOZOLV ODT?**

528 METOZOLV ODT is a prescription medicine used in adults:

- 529 • for 4 to 12 weeks to relieve heartburn symptoms of gastroesophageal reflux disease (GERD) when  
530 certain other treatments do not work.
- 531 • to relieve the symptoms of slow stomach emptying in people with diabetes.

532

533 It is not known if METOZOLV ODT is safe or works in children.

534

### 535 **Who should not take METOZOLV ODT?**

536 Do not take METOZOLV ODT if you:

- 537 • have stomach or intestine problems that could get worse with METOZOLV ODT, such as bleeding,  
538 blockage or a tear in your stomach or bowel wall
- 539 • have an adrenal tumor called pheochromocytoma
- 540 • are allergic to metoclopramide or any of the ingredients in METOZOLV ODT. See the end of this  
541 Medication Guide for a list of ingredients in METOZOLV ODT.
- 542 • take medicines that can cause uncontrolled movements, such as medicines for mental illness.
- 543 • have seizures

544

545

### 546 **What should I tell my doctor before taking METOZOLV ODT?**

547 Before you take METOZOLV ODT, tell your doctor if you:

- 548 • have kidney or liver disease
- 549 • have depression or mental illness
- 550 • have high blood pressure
- 551 • have heart failure or heart rhythm problems
- 552 • have diabetes. Your dose of insulin may need to be changed.
- 553 • have Parkinson’s disease
- 554 • have any other medical conditions
- 555 • drink alcohol
- 556 • are pregnant or plan to become pregnant. It is not known if METOZOLV ODT will harm your unborn  
557 baby.
- 558 • are breast-feeding or plan to breast-feed. METOZOLV ODT can pass into your milk and may harm your  
559 baby. You and your doctor should decide if you will take METOZOLV ODT or breast-feed. You should  
560 not do both.

561

562 **Tell your doctor about all the medicines you take, including prescription and non-prescription**  
563 **medicines, vitamins, and herbal supplements.** METOZOLV ODT and some medicines can affect each

564 other and may not work as well, or cause possible side effects. Do not start any new medicine while  
565 taking METOZOLV ODT until you talk with your doctor.

566

567 **Especially tell your doctor if you take:**

- 568 • another medicine that contains metoclopramide, such as REGLAN tablets, REGLAN ODT, or
- 569 metoclopramide oral syrup
- 570 • a blood pressure medicine
- 571 • a medicine for depression, especially a monoamine oxidase inhibitor (MAOI)
- 572 • an anti-psychotic medicine
- 573 • insulin
- 574 • medicines that can make you sleepy, such as anti-anxiety medicines, sleep medicines, and narcotics.

575

576 Ask your doctor or pharmacist if you are not sure if your medication is listed above.

577

578 Know the medicines you take. Keep a list of your medicines to show your doctor and pharmacist when  
579 you get new medicine.

580

581 **How should I take METOZOLV ODT?**

- 582 • METOZOLV ODT comes as a tablet that melts in your mouth.
- 583 • Take METOZOLV ODT exactly as prescribed by your doctor. Do not change your dose unless your
- 584 doctor tells you to.
- 585 • You should not take METOZOLV ODT for more than 12 weeks.
- 586 • Take METOZOLV ODT at least 30 minutes before eating and at bedtime.

587

588 To take METOZOLV ODT:

- 589 1. Leave the tablet in the sealed blister METOZOLV ODT pack until you are ready to take it.
- 590 2. Use dry hands to open a blister and take out a tablet. If the tablet breaks or crumbles throw it away
- 591 and take a new tablet out of the blister pack.
- 592 3. Put the tablet on your tongue right away. Let it melt and then swallow. You do not need water to
- 593 take METOZOLV ODT.

594

595 If you take too much METOZOLV ODT, call your doctor or Poison Control Center.

596

597 **What should I avoid while taking METOZOLV ODT?**

- 598 • Do not drink alcohol while taking METOZOLV ODT. Alcohol may make some side effects of
- 599 METOZOLV ODT worse, such as feeling sleepy.
- 600 • Do not drive, work with machines, or do dangerous tasks until you know how METOZOLV ODT
- 601 affects you. METOZOLV ODT may cause sleepiness.

602

603 **What are the possible side effects of METOZOLV ODT?**

604

605 **METOZOLV ODT can cause serious side effects, including:**

- 606 • **Abnormal muscle movements.** See “What is the most important information I should know about
- 607 METOZOLV ODT?”
- 608 • **Uncontrolled spasms of your face and neck muscles, or muscles of your body, arms, and legs**
- 609 **(dystonia).** These muscle spasms can cause abnormal movements and body positions. These spasms
- 610 usually start within the first 2 days of treatment. These spasms happen more often in children and
- 611 adults younger than 30.

612

613 • **Depression, thoughts about suicide, and suicide.** Some people who take METOZOLV ODT may  
614 become depressed. You may have thoughts about hurting or killing yourself. Some people who have  
615 taken metoclopramide products have ended their own lives (suicide).

616  
617 • **Neuroleptic Malignant Syndrome (NMS).** NMS is a rare but very serious condition that can  
618 happen with METOZOLV ODT. NMS can cause death and must be treated in a hospital. Symptoms  
619 of NMS include: high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, and  
620 increased sweating.

621 • **Parkinsonism.** Symptoms include slight shaking, body stiffness, trouble moving or keeping your  
622 balance. If you have Parkinson’s Disease, your symptoms may become worse while you are taking  
623 METOZOLV ODT.

624  
625 • **High blood pressure.** METOZOLV ODT can cause your blood pressure to increase.

626  
627 • **Too much body water.** People who have certain liver problems or heart failure and take  
628 METOZOLV ODT may hold too much water in their body (fluid retention). Tell your doctor right  
629 away if you have sudden weight gain, or swelling of your hands, legs, or feet.

630

631 **Call your doctor and get medical help right away if you:**

- 632 • feel depressed or have thoughts about hurting or killing yourself
- 633 • have high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, and increased
- 634 sweating
- 635 • have muscle movements you cannot stop or control
- 636 • have muscle movements that are new or unusual

637

638 **The most common side effects of METOZOLV ODT are:**

- 639 • headache
- 640 • nausea
- 641 • vomiting
- 642 • tiredness
- 643 • sleepiness

644

645 You may have more side effects the longer you take METOZOLV ODT and the more METOZOLV ODT  
646 you take.

647 You may still have side effects after you stop METOZOLV ODT. You may have symptoms from  
648 stopping (withdrawal) METOZOLV ODT such as headaches, and feeling dizzy or nervous.

649 Tell your doctor about any side effects that bother you or do not go away. These are not all the possible  
650 side effects of METOZOLV ODT.

651 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–  
652 FDA-1088.

653

654 **How do I store METOZOLV ODT?**

- 655 • Store METOZOLV ODT at room temperature, between 68° F to 77° F (20°C to 25°C).
- 656 • Keep METOZOLV ODT away from moisture.
- 657 • Throw away any METOZOLV ODT that is not used.

658 **Keep METOZOLV ODT and all medicines away from children.**

659

660 **General information about METOZOLV ODT**

661 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not  
662 use METOZOLV ODT for a condition for which it was not prescribed. Do not give METOZOLV ODT to  
663 other people, even if they have the same symptoms that you have. It may harm them.

664 This Medication Guide summarizes the most important information about METOZOLV ODT. If you  
665 would like more information about METOZOLV ODT, talk with your doctor. You can ask your doctor or  
666 pharmacist for information about METOZOLV ODT that is written for health professionals. For more  
667 information, call 1-866-669-7597.

668

669 **What are the ingredients in METOZOLV ODT?**

670 Active ingredients: metoclopramide hydrochloride

671 Inactive ingredients: gelatin, mannitol, mint flavoring, acesulfame potassium (artificial sweetener), and  
672 trace amounts of sodium chloride and sodium hydroxide

673

674

675 Salix Pharmaceuticals, Inc.

676 Morrisville, NC 27560, USA

677

678 This Medication Guide has been approved by the U.S. Food and Drug Administration.

679

680 VENART ###-#/ Sep 2009